THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 47

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte EUGENE B. DOWDLE

Appeal No. 95-0155
Application No. 07/890,335[1]

HEARD: August 5, 1998

Before WINTERS, GRON and OWENS, Administrative Patent Judges.

WINTERS, Administrative Patent Judge.

DECISION ON APPEAL

This appeal was taken from the examiner's decision rejecting claims 69, 70, 72 through 78, 80 through 84, 87

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[1] Application for patent filed May 26, 1992. According to applicant, this application is a continuation of Application No. 07/150,475, filed January 28, 1988; which is a continuation of Application No. 06/843,405, filed March 24, 1986; which is a continuation of Application No. 06/559,569, filed December 8, 1983; which is a continuation-in-part of Application No. 06/513,145, filed July 12, 1983, all of which were abandoned.

through 90, and 92 through 96, which are all of the claims remaining in the application.

REPRESENTATIVE CLAIMS

Claims 69 and 95, which are illustrative of the subject matter on appeal, read as follows:

69. A method of treatment or prophylaxis of thrombosis, embolism or other conditions where it is desired to produce fibrinolytic or proteolytic activity selectively in the presence of fibrin via the mechanism of plasminogen activation which comprises administering by injection or intravenously to a patient a plasminogen activator composition comprising a plasminogen activator component, said component being a human tPA/human pro-tPA couple composed of from 70 to 100% human pro-tPA and from 0 to 30% human tPA.

95. A pharmaceutical composition suitable for the treatment or prophylaxis of thrombosis or embolism which composition acts selectively in the presence of fibrin by means of local plasminogen activation and which is in dosage units for injection or intravenous infusion, said composition comprising:

(a) a human tPA/human pro-tPA couple composed of 70-100% human pro-tPA and up to 30% human tPA; and

(b) a physiologically compatible medium.

THE REFERENCES

In rejecting all of the appealed claims under 35 U.S.C. § 103, the examiner relies on the following reference:

Collen et al. 0 041 766 Dec. 16, 1981
(European Patent Application)

In taking the position that a person having ordinary skill in this art would have difficulty drawing a correlation between in vitro test results and utility in vivo, the examiner relies on the following reference:

D. Collen, "Synergism of Tissue-Type Plasminogen Activator (t-PA) and Single-Chain Urokinase-Type Plasminogen Activator (scu-PA) on Clot Lysis In Vitro and a Mechanism for this Effect," 57 Thrombosis and Haemostasis no. 3, 373 (1987).

THE ISSUE

As stated in the Examiner's Answer, page 2, section (4), the previously entered rejections under 35 U.S.C. § 112, first paragraph, and under 35 U.S.C. § 103 over the Reich et al. reference, have been withdrawn.

The sole issue on appeal is whether the examiner erred in rejecting claims 69, 70, 72 through 78, 80 through 84, 87 through 90 and 92 through 96 under 35 U.S.C. § 103 as unpatentable over European Patent Application 0 041 766.

DELIBERATIONS

Our deliberations in this matter have included evaluation and review of the following materials: (1) the instant specification, including all of the claims on appeal; (2) applicant's Appeal Brief, the Reply Brief, and the Supplemental Reply Brief; (3) the Examiner's Answer; and (4) the above-cited references relied on by the examiner.

On consideration of the record, including the above-listed materials, we reverse the examiner's rejection under 35 U.S.C. § 103.

DISCUSSION

Initially, we agree with the examiner's finding that the claimed pharmaceutical composition and method are not described by European Patent Application 0 041 766 within the meaning of 35 U.S.C. § 102.

We have carefully reviewed European Patent Application 0 041 766 in its entirety, including the claims therein. At best, this reference suggests that pro-tPA has "sufficient binding capacity to fibrin" and behaves "in the same way" as tPA when subjected to immunodiffusion analysis and quenching experiments (European Patent Application 0 041 766, Example 4, last paragraph). This reference teaches the use of tPA, not pro-tPA, as a pharmaceutical. See claims 18 and 19 of European Patent Application 0 041 766, drawn to a pharmaceutical composition and a method of preparing a pharmaceutical composition, which depend from claims 1 through 3 but exclude the subject matter of claim 4 drawn to pro-tPA.

Contrary to what a person having ordinary skill would have expected at the time the invention was made, per the teachings of European Patent Application 0 041 766, applicant's specification describes the superiority of pro-tPA

over tPA in treating thrombosis and related diseases. In showing the characteristics of pro-tPA, and in predicting its superior performance in vivo, applicant sets forth in vitro data in the specification (Examples 8 and 10). The 1986 and 1988 publications of Rao and Rijken, respectively, further support the fact stated in the specifi-cation that pro-tPA is more advantageous than tPA as a pharma-ceutical for treating thrombosis and related diseases. The Rao and Rijken publications (copies attached to the Supplemental Reply Brief) provide evidence that pro-tPA is clinically superior to tPA when administered in vivo to human patients.

Having considered all the evidence of record, including the Rao and Rijken publications, we find that the claimed subject matter possesses unexpectedly superior properties. On this basis, the rejection of claims 69, 70, 72 through 78, 80 through 84, 87 through 90 and 92 through 96 under 35 U.S.C. § 103 as unpatentable over European Patent Application 0 041 766 is reversed.

REVERSED

SHERMAN D. WINTERS)
Administrative Patent Judge)
)

TEDDY S. GRON Administrative Patent Judge	)	BOARD OF PATENT APPEALS AND INTERFERENCES
TERRY J. OWENS Administrative Patent Judge	)	

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